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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/786,502	05/18/2001	Michel Sadclain	MSK.P-040	1539

52334 7590 08/04/2006  
Marina Larson & Associates LLC  
re: MSK  
P. O. BOX 4928  
DILLON, CO 80435-4928

EXAMINER

RAWLINGS, STEPHEN L

ART UNIT	PAPER NUMBER
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1643

DATE MAILED: 08/04/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<p align="center"><b>Advisory Action</b> <b>Before the Filing of an Appeal Brief</b></p>	<b>Application No.</b> 09/786,502	<b>Applicant(s)</b> SADELAIN ET AL.	
	<b>Examiner</b> Stephen L. Rawlings, Ph.D.	<b>Art Unit</b> 1643	

**--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

THE REPLY FILED 25 July 2006 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:

- a) ☐ The period for reply expires \_\_\_\_\_ months from the mailing date of the final rejection.  
 b) ☒ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### NOTICE OF APPEAL

2. ☐ The Notice of Appeal was filed on \_\_\_\_\_. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

#### AMENDMENTS

3. ☐ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because  
 (a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);  
 (b) ☐ They raise the issue of new matter (see NOTE below);  
 (c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or  
 (d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: \_\_\_\_\_. (See 37 CFR 1.116 and 41.33(a)).

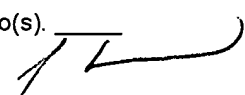
4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).  
 5. ☐ Applicant's reply has overcome the following rejection(s): \_\_\_\_\_.  
 6. ☐ Newly proposed or amended claim(s) \_\_\_\_\_ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).  
 7. ☒ For purposes of appeal, the proposed amendment(s): a) ☐ will not be entered, or b) ☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.  
 The status of the claim(s) is (or will be) as follows:  
 Claim(s) allowed: \_\_\_\_\_.  
 Claim(s) objected to: \_\_\_\_\_.  
 Claim(s) rejected: 1-3, 5, 12, 13, 16, 25, 26, 28-30, and 32.  
 Claim(s) withdrawn from consideration: 7, 8, 10, 11 and 21-24.

#### AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).  
 9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing of good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).  
 10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

#### REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because:  
See Continuation Sheet.  
 12. ☐ Note the attached Information Disclosure Statement(s). (PTO/SB/08 or PTO-1449) Paper No(s). \_\_\_\_\_  
 13. ☒ Other: See Continuation Sheet.

  
 Stephen L. Rawlings, Ph.D.  
 Primary Examiner  
 Art Unit 1643

Continuation of 11. does NOT place the application in condition for allowance because:

Applicant's arguments with regard to the rejection of the claims under 35 U.S.C. § 112, first paragraph, as lacking an adequate written description, have been carefully considered but not found persuasive. As explained in the preceding Office action, the claimed invention is a fusion protein comprising an scFv and a cytoplasmic domain. According to the disclosure, the "cytoplasmic domain" is a molecule that "functions as a transducer of a mammalian immune response in the presence of a costimulatory factor". Although the disclosure includes a description of a few members of such a genus of "cytoplasmic domains", they are not deemed representative of the genus, as a whole, since they share no particularly identifying features that would permit the skilled artisan to immediately envision, recognize or distinguish at least a substantial number of the members of the genus. Without the "cytoplasmic domain", the claimed invention cannot be made; therefore, without an adequate description of the genus, the disclosure would not reasonably convey to the skilled artisan that Applicant had possession of the claimed invention at the time the application was filed. It is noted that Applicant has newly cited *In re Fuetterer*, suggesting the decision by the CCPA supports their assertion that contrary to the rejection, the disclosure should be regarded as adequately descriptive. In response, the Court indicated that the inorganic salt to which the claims are directed does not constitute the invention, since the invention is the combination claimed (i.e., a rubber stock composition), not the discovery that certain inorganic salts have colloid suspending properties. The present claims are directed to a fusion protein comprising a "cytoplasmic domain", which is a molecule that "functions as a transducer of a mammalian immune response in the presence of a costimulatory factor". Thus, in this instance and perhaps in contrast to the issue considered by the Court, the "cytoplasmic domain" is an integral and functional part of the disclosed and claimed invention. As such, it is believed that Applicant's arguments have been carefully considered and not found persuasive for the reasons reiterated herein or made already of record by the preceding Office action. See section 8 at pages 4-11 of the Office action mailed May 25, 2006.

Applicant's arguments with regard to the rejections of the claims under 35 U.S.C. § 103(a) have been carefully considered but not found persuasive for the reasons already set forth in the preceding Office action. See sections 9, 10, and 11 at pages 12-15 of the of the Office action mailed May 25, 2006. Applicant is reminded that with regard to the rejection set forth in section 14 beginning at page 8 of the Office action mailed September 21, 2005, for example, the only element of the claimed invention not expressly taught by the primary reference is the requisite binding specificity of the scFv that binds a tumor antigen; nonetheless, this deficiency is met by the secondary reference, and as such, contrary to any argument otherwise, the invention would have been obvious to one ordinarily skilled in the art at the time of the invention. Moreover, one ordinarily skilled in the art at the time of the invention would have been motivated to produce the claimed invention for the reasons set forth in the rejection.

Applicant's submission of a copy of the cited publication by Guest et al. is acknowledged, and although Applicant's arguments based upon the teachings of this reference have been carefully considered, they have not been found persuasive because the prior art teaches the functional and effective use of a connector comprising a CD8 hinge to adjoin a scFv that binds a tumor-associated antigen and a cytoplasmic domain of the zeta chain of CD3 or a cytoplasmic domain of CD28. See, e.g., Figure 1 of either U.S. Patent Application Publication No. 2003/6077249 A1 (Bebbington et al.) or WO 97/23613 A2 (Bebbington et al.).

Applicant's arguments with regard to the provisional rejection of the claims under the judicially created doctrine of obviousness-type double patenting have been carefully considered but not found persuasive for the reasons already set forth in the preceding Office action. See section 12 at pages 15 and 16 of the of the Office action mailed May 25, 2006.

Continuation of 13. Other: Applicant's amendment to the specification has obviated the ground of objection set forth in section 7 of the Office action mailed September 21, 2005.